510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. Submitter Information:

CooperVision, Inc.
711 North Road
Scottsville, NY 14546

Contact Person: Bonnie Tsymbal
Manager, Regulatory Affairs

Telephone: (716) 264-3210
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Date Prepared: August 16, 2000

2. Device Name:

Common Name: Soft (hydrophilic) Contact Lens

Trade/Proprietary Name: Frequency Multifocal/P and Frequency Multifocal/C (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear

Device Classification: Class II

3. Predicate Device:

The predicate devices are the UltraVue/P and C (methafilcon A) (Multifocal) Manufactured by Opti-Center and Frequency 55 (methafilcon A) (Sphere and Asphere) Soft (hydrophilic) contact lenses for daily wear manufactured by Aspect Vision. The predicate devices were cleared under K001227 and K973063 respectively. The devices were selected as the predicate devices based on the material, intended use and design.

4. Device Description:

The ***Frequency Multifocal*** (methafilcon A) soft (hydrophilic) contact lenses are available as a multifocal lens with an aspherical front surface and spherical back surface for the correction of visual acuity in presbyopic persons who are myopic or hyperopic. In its hydrated state the lens covers the cornea and a portion of the adjacent sclera. The Frequency Multifocal/P and Frequency Multifocal/C are designed with two multifocal zones, as well as the edge shape being optimized to provide comfort without sacrificing tensile strength. The Frequency Multifocal/P has a spherical central zone for the correction of distance vision and an aspherical annular zone for the correction of intermediate and near vision. The Frequency Multifocal/C has a spherical central zone for the correction of near vision and an aspherical annular zone for the correction of intermediate and distance vision. The lenses are available in clear or with a light blue handling tint.

The lens material, methafilcon A, is a random copolymer of hydroxyethylmethacrylate and methacrylic acid. The lenses are tinted from edge to edge for visibility purposes with the color additive, Reactive Blue No. 4.

The physical properties of the lens are:

- Refractive Index: 1.41
- Light Transmittance: >96%
- Surface Character: Hydrophilic
- Water Content: 55%
- Oxygen Permeability: 19.7×10^{-11} $(cm^2/sec)(ml\ O_2/ml \times mmHg)$ at 35°C
  (Fatt method for determination of oxygen permeability)

5. Indications for Use:

Frequency Multifocal lenses are indicated for daily wear. They are indicated for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia or hyperopia and are presbyopic. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

When prescribed for Frequent/Planned Replacement Wear, the Frequency Multifocal/P and C lenses are to be cleaned, rinsed and disinfected each time they are removed from the eye and discarded after the recommended wearing period prescribed by the eye care practitioner.

6. Substantial Equivalence:

Comparison to Predicate Device

	Frequency Multifocal P & C (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear	UltraVue P & C (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear **(Predicate Device)** Opti-Center	Frequency (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear **(Predicate Device)** Aspect Vision
Lens Material	methafilcon A	methafilcon A	methafilcon A
Material Classification	Group 4 >50% ionic polymer	Equivalent	Equivalent
Indication	Myopia, hyperopia and presbyopia	Myopia, hyperopia and presbyopia	Myopia and Hyperopia
Water Content	55%	55%	55%
Light Transmittance	>96%	Approximately 98%	>96%
Dk (35° C)	19.7×10^{-11}	18.8×10^{-11}	19.7×10^{-11}
Powers	+20.00 to –20.00 D	+20.00 to –20.00 D	+20.00 to –20.00 D
Tint	Reactive Blue #4	Phthalocynine Blue	Reactive Blue #4
Manufacturing Method	Fully Molded or Molded Back Surface/Lathed Front Surface	Lathe Cut	Fully Molded or Molded Back Surface/Lathed Front Surface
Lens Design	Multifocal	Multifocal	Sphere or Asphere
Packaging	Blister Pack	Glass Vial/Crimp Seal	Blister Pack

The Frequency Multifocal/P and C (methafilcon A) Soft (hydrophilic) Contact Lens will be manufactured according to specified process controls and an ISO 9001/EN46001 and CGMP quality assurance program currently in place. The established safety profile (preclinical, toxicological, chemical/optical) of the Frequency Multifocal/P and C are equivalent to the UltraVue/p and C and the Frequency 55.

Being similar with respect to indications for use, materials and comparable physiochemical properties to the predicate devices, this meets the requirements per section 510(k) of the act regarding substantial equivalence and does not raise questions of safety and effectiveness than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 3 2000

Ms. Bonnie Tsymbal
Manager, Regulatory Affairs
CooperVision, Inc.
711 North Road
Scottsville, NY 14546

Re: K002625
Trade Name: Frequency Multifocal/P and Frequency Multifocal/C (methafilcon A)
Soft (hydrophilic) Contact Lens for Daily Wear
Regulatory Class: II
Product Code: LPL
Dated: August 22, 2000
Received: August 23, 2000

Dear Ms. Tsymbal:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

CooperVision

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Indication for Use Statement

510(k) Number: K002625

Device Name: Frequency Multifocal

Indication for Use:

Frequency Multifocal lenses are indicated for daily wear. They are indicated for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia or hyperopia and are presbyopic. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

Frequent/Planned Replacement Wear

When prescribed for Frequent/Planned Replacement Wear, the Frequency Multifocal/P and C lenses are to be cleaned, rinsed and disinfected each time they are removed from the eye and discarded after the recommended wearing period prescribed by the eye care practitioner.

PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel W. C. Brown, PH. D.

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K002625

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter _____